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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,637	12/17/2001	Qi Wang	16515.106	7557

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,637	WANG ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-24* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *17 March 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-24 are pending and are examined in the instant action.

Information Disclosure Statement

2. Applicant's IDS filed 17 March 2003 is acknowledged and a signed copy included herewith.

Objections

3. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112-written description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 5-15 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a (Claim 1) transformed soybean plant cell containing a nucleic acid molecule that comprises in the 5' to 3' direction: a promoter having a nucleic acid sequence that is at least 94% identical to SEQ ID NO: 1, operably linked to a structural nucleic acid sequence; where in the promoter is heterologous with respect to the structural nucleic acid sequence, where the sequence is at least 95% identical, where the sequence is at least 99% identical, and where the sequence is SEQ ID NO: 1. The claims are also drawn to the soybean plant cell of Claim 1 where the structural nucleic acid sequence is one of the list of 23 sequences listed in claim 5, where in the molecule further comprises a 5' leader sequence, where the 5' leader sequence is selected from the group consisting of Arcelin-5 5', dSSU 5', PetHSP70 5', and GmHSP17.9 5', where the nucleic acid molecules further comprises a 3' untranslated region selected from the group consisting of Arcelin-5 3', NOS 3', E9 3', ADR12 3', 7Salpha' 3', 11S 3', and albumin 3'. The claims are also drawn to the plant cell of claim 1, where the promoter expresses the structural nucleic acid sequence in an amount greater than 2.5%(w/w) of the total cellular RNA or protein, where the promoter expresses the structural nucleic acid sequence in an amount greater than 5.0%(w/w) of the total cellular RNA or protein, and where promoter expresses the structural nucleic acid sequence in an amount greater than 10%(w/w) of the total cellular RNA or protein. The claims are also drawn (claims 13-24) to the transgenic soybean plant containing all the elements recited for claims 1-12.

Applicants present the complete promoter sequence as set forth in SEQ ID NO:1 (specification, p. 5, lines 12-13), which is a truncated P. vulgaris exotic genotype G02771 Arcelin-5 promoter. Applicants do not describe any polynucleotide promoter sequences that are 99%, 95% or 94% identical to SEQ ID NO: 1.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide promoter sequences which are at least 94% identical to SEQ ID NO:1. Applicants only describe a single promoter sequence (SEQ ID NO:1). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for SEQ ID NO: 1 promoter activity, it remains unclear what features identify a polynucleotide of SEQ ID NO: 1 other than the SEQ ID NO: itself. Since the genus of promoter sequences of SEQ ID NO: 1 has not been described by

specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that are 94% identical with SEQ ID NO: 1 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 1, as well as sequences having no promoter activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claim Rejections - 35 USC § 112 Enablement

6. Following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3 and 5-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims drawn to a transformed soybean plant cell containing a nucleic acid molecule that comprises in the 5' to 3' direction: a promoter having the nucleic acid sequence SEQ ID NO: 1, operably linked to a structural nucleic acid sequence; where in the promoter is heterologous with respect to the structural nucleic acid sequence, is not enabled for the soybean plant cell where the sequence is at least 94%, 95% or,99% identical to SEQ ID NO: 1. The specification, while being enabled for the soybean plant cells, is not enabled for any soybean plants. The specification does not enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The breadth of the claims is discussed above in Written Description.

Guidance: Applicant describes (specification, Example 3, page 41 and Figure 2) protein analysis from soybean cotyledons bombarded with plasmid pMON55527 (containing the promoter of SEQ ID NO: 1 operably linked to a GUS coding sequence) in a transient assay. Applicant do not teach or give guidance for a promoter of any percent identity less than 100% of SEQ ID NO: 1.

The specification fails to provide guidance for the other polynucleotides encompassed by the claims for promoter of any percent identity less than 100% of SEQ ID NO: 1. Applicants fail to teach which nucleotides can be altered, mutated or deleted and still have the promoter activity of SEQ ID NO:1. Nor are sequences of less than 100% sequence identity or "functional fragments" of a promoter predictable as to their expression characteristics. Benfry, et al, US

patent 5, 110, 732, issued 5 May 1992, shows that various fragments of the CaMV 35S promoter exhibit different expression characteristics in tobacco tissue. Benfry further teaches that one fragment exhibits selective expression in root tissue and in the radical of the seed; whereas, another fragment exhibits constitutive expression in plant tissue other than root tissue.

Applicant gives no guidance re a transformed soybean plant containing a nucleic acid molecule that comprises in the 5' to 3' direction: a promoter having the nucleic acid sequence SEQ ID NO: 1, operably linked to a structural nucleic acid sequence; where in the promoter is heterologous with respect to the structural nucleic acid sequence expressing.

The regeneration of plants from explants (Applicant teaches transgenic soybean cotyledons) is unpredictable, and explant selection is critical for successful plant regeneration. See Tisserat, in Plant Cell Culture, ed R.A. Dixon, 1985, IRL Press, Oxford, pages 79-105, especially page 80, Table 1, page 82, and Table 4, pages 85-90. Also see Journal of Plant Nutrition, 1994, vol. 17, no. 4, pages 549-560. This study show that salt tolerance screened at the callus level is not expressed in regenerated plants. This speaks to the unpredictability of extrapolating phenotypic characteristics from those of cell level to the characteristics of regenerated plants.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 as probes or by designing primers to

undisclosed regions of SEQ ID NO:1 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those polynucleotides that when transformed into plant cells or plants, function as promoter sequences to produce the expression pattern and stoichiometry characteristics of SEQ ID NO: 1, in soybean cells and plants.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 2, 3, 5-15, and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goossens, et. al., Plant Physiol., August 1999, vol. 120, pages 1095-1104 (IDS) and NCBI accession Z50202, August 1998, in view of Chee et.al. Transformation of Soybean (Glycine max) via Agrobacterium

tumefaciens and analysis of transformed plants, in Methods in Molecular biology, 1995, Vol. 44, Humana Press Inc, Totowa, NJ, pages 101-119.

Goossens, et. al., teach a DNA sequence 99.7% identical to SEQ ID NO:1 (see sequence search pages of June 16, 2004, included). This is the DNA sequence employed in the Goossens, et. al., 1999 publication supra. Goossens et. al. obtained and characterized the Arcelin 5 gene from Phaseolus vulgaris, after which it was transformed into Phaseolus acutifolium (Tepary bean), which is also a legume plant and is very similar to P. vulgaris.

Goossens et. al. teach a transformed Phaseolus acutifolium (Tepary bean) transgenic (page 1100, Table II, see data for lines B1b and B52b) for an arcelin promoter least 94%, 95%, and 99% identical to SEQ ID NO: 1, operably linked to a seed lectin structural gene (the ARC5 coding sequence) where the promoter is heterologous to the structural gene. Applicant's specification defines (page 7, lines 19-24) a heterologous " promoter as being heterologous with respect to a coding sequence if such a combination is not found in nature". The arcelin promoter of Goossens has been modified from that of nature and therefore, is heterologous with respect to the coding sequence. The nucleic acid of Goossens et. al. also contains a 5' leader sequence (Genebank accession Z50202, page 2 of 3, called "5'UTR") of Arcelin-5 (see sequence numbers 1822-1834 of Z50202) and the 3' untranslated region of Arcelin 5 (see sequence numbers 2618-2754, called "3'UTR" of Z50202). Goossens et. al. further teaches the transformation frequency plant cell where the promoter expresses the structural nucleic acid in

an amount of 25% (w/w) of the total cellular protein (Table II, see "Arc5 protein level" for lines B1b and B52b, where the percentage ranges from 15-25%).

Goossens et. al. do not teach transgenic soybean cells and plants. Chee et. al. teach the transformation of soybean. It would have been obvious to one of skill in the art, at the time of the invention was made, to substitute for the Phaseolus acutifolium (Tepary bean) of Goossens et. al. the soybean of Chee et al. Goossens et. al. provides motivation to do so saying "that their work indicates that the 5' and 3' flanking sequence of the arc5-I seed storage protein gene contain most, if not all, the essential information for correct development and spatial regulation and exceptionally high accumulation of arcelin-5 protein in transgenic plants. Moreover, these expression signals appear to function efficiently in two different plant species taxonomically not closely related" (p.1102, final ¶). The phaseolin plant of Goossens et. al. is a leguminous plant, closely related to soybeans. Therefore one skilled in the art would have been motivated to so, with a reasonable expectation of success. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

Remarks

10. Claims 1-3 and 5-24 are not allowed, given the prior art of a DNA sequence 99.7% identical to SEQ ID NO: 1. Applicant should note that the prior art sequence has just two mismatches in 1821 base pairs. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if

rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1638
June 28, 2004

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